(B) Are health plans and fail to report information concerning sanctions or other adverse actions imposed on providers as required to be reported to the Healthcare Integrity and Protection Data Bank (HIPDB) in accordance with section 1128E of the Act;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters, symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act or §489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services, or who engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses, or that do not meet the requirements for physician incentive plans for Medicare specified in §§417.479 (d) through (i) of this title;

(viii) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

(ix) Present or cause to be presented a bill or claim for designated health service (as defined in §411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under §411.353 of this title;

(x) Have collected amounts that they know or should know were billed in violation of §411.353 of this title and have not refunded the amounts collected on a timely basis;

(xi) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of §411.353 of this title; or

(xii) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act.

[57 FR 3345, Jan. 29, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 48566, Sept. 22, 1994; 60 FR 16583, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 64 FR 39428, July 22, 1999]

§1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in §1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service for which payment may be made under the Medicare, Medicaid, Maternal and Child Health Services Block Grant, or Social Services Block Grant programs.

(a) An item or service for which payment may be made under Medicare, or

(b) An item or service for which medical assistance is provided under a State plan for medical assistance, or

(c) An item or service for which payment may be made under the Maternal and Child Health Services Block Grant program.

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in the Medicare program or in a State health care program, and that items or services furnished or ordered by such person are not reimbursed under such programs.

General Counsel means the General Counsel of the Department or his or her designees.

HCFA means the Health Care Financing Administration.

Inspector General means the Inspector General of the Department or his or her designees.

Item or *service* includes (a) any item, device, medical supply or service claimed to have been provided to a patient and listed in an itemized claim for program payment or a request for payment, and (b) in the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's or other health care practitioner's provision of, or failure to provide health care services, and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in §1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Program means the Medicare, Medicaid, Maternal and Child Health Services Block Grant, and Social Services Block Grant programs.

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with §1003.102(b)(9) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996]

§ 1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed;